Randomized controlled study of ureteral catheter placement for prevention of injury during laparoscopic gynaecologic surgery.

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Abstract

This study explored the use of ureteral catheter placement to prevent injury during laparoscopic gynaecologic surgery. Sixty patients who underwent laparoscopic surgery were randomly divided into test and control groups. The operative time, amount of intraoperative bleeding, time until return to routine activity, time until recovery of gastrointestinal function, length of hospital stay, need for postoperative analgesia, and incidence rate of ureteral injury were evaluated in the two groups. There were no ureteral injuries in the test group, but 1 patient in the control group had a ureteral injury (3.6%) (P<0.05). The operative time and amount of intraoperative bleeding were significantly different between the two groups (P<0.05), but there were no statistically significant differences in need for postoperative analgesia, time until return to routine activity, time until recovery of gastrointestinal function, and length of hospital stay (P>0.05). Pre-operative placement of a ureteral catheter can prevent injury during laparoscopic gynaecologic surgery, decrease the amount of intraoperative bleeding, and reduce the operative time. Preoperative ureteral catheter placement should be routinely performed in laparoscopic gynaecologic surgery, especially in patients with pelvic adhesions.

Keywords: Cervical cancer, Ovarian cancer, Laparoscope.

Materials and Methods

Clinical data

This study enrolled 60 female patients with a mean age of 53.6 ± 18.4 years and body mass index of 23.8 ± 2.5; disease duration ranged from 3 days to 6 months, and included 34 cases of cervical cancer (22 stage I and 13 stage II cases, based on International Federation of Gynaecology and Obstetrics criteria), 23 cases of ovarian cancer (12 stage I and 11 stage II cases), and 3 cases with multiple myomata. This was a prospective, randomized controlled, single-blind trial. The 60 cases were randomly divided into a test group (32 cases) and a control group (28 cases), and the randomizing scheme was hidden: the random sequence was only known to one clinician, and the cases were numbered in order. Age, body mass index, disease duration, and tumor stage showed no statistical differences between the two groups. All patients underwent preoperative abdominal B-scan ultrasonography, transvaginal color Doppler ultrasonography, computed tomography, electrocardiography, and X-ray and laboratory examinations; biopsy, intravenous urography, and magnetic resonance imaging were selectively performed. This study was approved...
by the ethics committee of our hospital, and patients provided signed informed consent.

**Surgical procedures**

Patients were routinely placed in the lithotomy position, and ureteral catheters and gastric tubes were inserted under general endotracheal anesthesia. Patients in the test group underwent preoperative insertion of a 6 F ureteral catheter by a urologic surgeon; placement was unilateral in 25 cases and bilateral in 7 cases. Total laparoscopic hysterectomy was performed in 17 cases, and 13 cases underwent radical hysterectomy and extirpation of pelvic lymph nodes. All operations were performed by experienced surgeons with expertise in laparoscopy. The details of surgical methods have been described in the literature [17]. If the pathology results indicated pelvic lymph node metastasis, patients would undergo adjunctive radiotherapy or chemotherapy, based on the pathological type.

**Observational indices and statistical analysis**

Observational indices included the operative time, amount of intraoperative bleeding, need for postoperative analgesia, time to dietary resumption, time until return to routine activity, length of hospital stay, and the incidence rate of complications. Operative time was defined as that from skin incision to closure. SPSS 12.0 software was used for statistical analysis.

**Results**

Successful surgery was performed in 60 cases without need for blood transfusion or conversion to an open procedure. One case (3.6%) in the control group had a ureteral injury, for an incidence rate of 1.7% (1/60), and was treated by ureterovesical reimplantation. There were statistically significant differences in operative time, amount of bleeding, and incidence rate of complications between the two groups. The operative time was 107.6 ± 25.7 min in the test group and 129.5 ± 23.5 min in the control group (P<0.05); the amount of intraoperative bleeding was 176.6 ± 59.2 ml in the test group and 217.3 ± 71.3 ml in the control group (P<0.05). The need for postoperative analgesia, the time until return to routine activity, the time to recovery of gastrointestinal function, and the length of hospital stay showed no statistically significant differences. The analgesic dose was 35.8 ± 26.1 mg in the test group and 33.4 ± 27.3 mg in the control group (P>0.05); the time until return to routine activity was 20.7 ± 3.6 h in the test group and 21.3 ± 4.2 h in the test group (P>0.05); the time to recovery of gastrointestinal function was 21.3 ± 4.2 h in the test group and 20.9 ± 3.9 h (P>0.05) in the control group (P>0.05); and the postoperative length of hospital stay was 7.1 ± 1.4 days in the test group and 7.3 ± 1.1 days in the control group (P>0.05) (Table 1). There was no case with incision liquefaction or infection in either group. The median follow-up time was 11 months, ranging from 7 to 19 months. There was no case with incisional hernia, and no evidence of tumor recurrence or metastasis, but 1 case was found to have a ureteral injury on follow-up at 12 months, without uronephrosis or vesicoureteral reflux.

**Table 1. Comparison of test group and control group (n1=32, n2 =28, ±s).**

<table>
<thead>
<tr>
<th>Observational indices</th>
<th>Test group</th>
<th>Control group</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Operation time (min)</td>
<td>107.6 ± 25.7</td>
<td>129.5 ± 23.5</td>
<td>&lt;0.05</td>
</tr>
<tr>
<td>The amount of bleeding during the operation (ml)</td>
<td>176.6 ± 59.2</td>
<td>217.3 ± 71.3</td>
<td>&lt;0.05</td>
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<tr>
<td>Postoperative analgesic dose (mg)</td>
<td>35.8 ± 26.1</td>
<td>33.4 ± 27.3</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Out-of-bed activity time (hours)</td>
<td>20.7 ± 3.6</td>
<td>33.4 ± 27.3</td>
<td>&gt;0.05</td>
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<tr>
<td>Recovery time of gastrointestinal function (hours)</td>
<td>21.3 ± 4.2</td>
<td>20.9 ± 3.9</td>
<td>&gt;0.05</td>
</tr>
<tr>
<td>Hospital stays (days)</td>
<td>7.1 ± 1.4</td>
<td>7.3 ± 1.1</td>
<td>&gt;0.05</td>
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</table>

**Discussion**

As the ureter is very close to the rectum and female reproductive system, iatrogenic ureteral injury commonly occurs in pelvic surgery and endoscopy, but is most common in gynaecologic surgery. Previous literature reported that 78%-82% [18] of injuries in gynaecologic surgery involved the ureter. With the widespread use of laparoscope technique in gynaecology, the number of cases with ureteral injury has increased, and the incidence rate of ureteral injury in laparoscopic surgery ranges from 0.3% to 3.8% [19-22]. In both open and laparoscopic surgery, the effective prevention of iatrogenic ureteral injury and its early identification and repair are frequently discussed topics. The benefit of preventive ureteral catheterization in complex laparoscopic gynaecologic procedures remains controversial, but most authors support preventive catheterization [23,24]. Some researchers have also performed non-selective preventive ureteral catheterization, which does not prevent ureteral injuries, or even might increase the incidence of urinary tract infections and other complications [25,26].

Our prospective, randomized controlled study showed that the operative time and amount of intraoperative bleeding were clearly decreased in the test group. There was only 1 case of ureteral injury in the control group, and none in the test group, which indicated that preoperative ureteral catheter placement can reduce the operative time and amount of bleeding, as well as the incidence rate of ureteral injury. After analysing video data and reviewing the operations, we found that the catheterized ureter was easily identified during surgery. The advantages of preoperative catheter placement are as follows. (1) A stent can keep the ureter expanded, so that it is easily identified; it was similarly reported [27,28] that prophylactic ureteral catheterization could help in the intraoperative identification of the ureter, thus preventing injuries during laparoscopic hysterectomy. (2) A stent can increase the firmness of the ureter, making it clearly visible during surgery.
Routine preoperative ureteral catheterization should also be associated with blind dissection. (3) A stent can emphasize the boundary between the ureter and surrounding tissues. (4) A ureteral stent can enable early identification of a ureteral injury, as the stent would be exposed at the time of injury. (5) A ureteral stent can avoid problems associated with blind dissection. Routine preoperative ureteral catheterization should also be performed for laparoscopic surgery in patients with pelvic adhesions.

Conflicts of Interest
All of the authors declare that they have no conflicts of interest regarding this paper.

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